REMARKS

Examination of claims 5-8 is reported in the present Office Action. Claims 5-8 are rejected under 35 U.S.C. § 112, first paragraph. Claims 1-4 and claims 9-14, which are directed to a non-elected invention, are withdrawn from consideration. The rejection is addressed below.

Support for the Amendments

Support for the amendments is found throughout the specification as originally filed. For example, support for the amendment of claim 5, which now recites "Testis Inhibitor of Apoptosis protein" is found at page 18, lines 8-9, and at page 2, lines 4-6; support for the amendment of claim 5, which now recites "an isolated polypeptide having at least 95% amino acid identity to human TIAP" is found at page 12, lines 12-14; and support for the amendment of claim 5, which now recites "comprising a BIR domain" is found at page 11, lines 14-18.

Rejection under 35 U.S.C. § 112, first paragraph

Written description

Claims 5-7, which now provide screening methods for compounds that modulate inhibition of apoptosis by TIAP, are rejected as lacking an adequate written description. The Examiner asserts that applicants have failed to show that they were in possession of

the invention as broadly claimed at the time the application was filed. As detailed below, this rejection is overcome by the present amendment.

The invention as presently claimed requires a TIAP polypeptide having at least 95% amino acid identity to SEQ ID NO:2 and containing a BIR domain. With respect to rejected claims 5-7, the method involves contacting the TIAP polypeptide with a candidate compound and determining the ability of the candidate compound to interact with the TIAP polypeptide, where a candidate compound that interacts with the TIAP polypeptide is identified as a compound that modulates inhibition of apoptosis by TIAP. Applicants plainly describe such methods in the application as originally filed. For example, methods of identifying TIAP homologs are described at page 24, line 24, to page 25, line 25, under the heading, "Cloning of Additional TIAP genes;" methods of compound screening and detecting polypeptide interactions are described at page 31, lines 1-26, under the heading, "Screening for Compounds Affecting TIAP Biological Activity."

Applicants submit that their specification provides a written description of the presently claimed invention in sufficient detail to satisfy the standard set by the Federal Circuit in *Lilly,* 119 F.3e 1559, 43 USPQ2d 1398. This case specifically states that the written description of a genus of DNA may be achieved by a "recitation of structural features common to members of the genus." *Lilly,* 43 USPQ2d 1398, 1406. In light of the Examiner's suggestions, the claims now recite a high degree of structural homology to

SEQ ID NO:2, and recite a characteristic structural feature, i.e., a BIR domain, which applicants disclose is common to IAP polypeptides, including XIAP and TIAP (Page 18, lines 1-7, and Figures 4B and 5). Applicants describe BIR domains in the specification as originally filed, for example, at page 11, lines 14-18, and at Figures 4B and 5.

Applicants' specification therefore provides a description of the methods encompassed by the claims in a form consistent with the standard set out in *Lilly*. Thus, the written description rejection should be withdrawn.

Enablement

Claims 5-8 are rejected under 35 U.S.C. 112, first paragraph, as lacking enablement. The Examiner bases this rejection on the assertion that applicants have failed to enable a method for screening compounds that modulate the biological activity of any and all variants of TIAP polypeptides. This rejection is also overcome by the present amendment.

Rejected claims 5-7, require a polypeptide having at least 95% amino acid identity to human TIAP (SEQ ID NO: 2) and comprising a BIR domain. The skilled artisan, provided with applicants disclosure of SEQ ID NO:2 and applicants' specification could clearly practice the methods of the present invention given that the claimed methods are now limited to sequences having a high degree of structural homology and a characteristic structural feature. Thus, the enablement rejection should also be withdrawn.

Rejection under 35 U.S.C. 112, second paragraph

Claims 5-8 are further rejected as indefinite. The Examiner asserts that the claims are indefinite because (i) it is unclear what biological activity of TIAP would be modulated by the interaction of TIAP with the candidate compound; and (ii) it is unclear whether the claimed method would be carried out *in vitro* or *in vivo*. This rejection is overcome by the present amendment as detailed below.

With respect to TIAP biological activity, the claims now require that the candidate compound modulates inhibition of apoptosis by TIAP.

With respect to the claimed method reading on a TIAP polypeptide *in vitro* or *in vivo*, claim 5 now requires detection of binding between the candidate compound and an isolated TIAP polypeptide. Thus, the indefiniteness rejection may also be withdrawn.

CONCLUSION

Applicants submit that this case is in condition for allowance, and such action is respectfully requested. If the Office does not concur, a telephonic interview with the undersigned is hereby requested.

If there are any charges or any credits, please apply them to Deposit Account No. 03-2095.

Respectfully submitted,

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Kristina Bieker-Brady, Ph.D.
Reg. No. 39,109

Clark & Elbing LLP
101 Federal Street
Boston, MA 02110
Telephone: 617-428-0200
Facsimile: 617-428-7045